



May 16, 2010

Georgina Verdugo
Director
Office of Civil Rights
US Department of Health and Human Services
Attention: HITECH Accounting of Disclosures
Hubert H. Humphrey Building, Room 509F
200 Independence Avenue, SW
Washington, DC 20201

Re: HITECH Accounting of Disclosures
Request for Information—May 3, 2010

Dear Ms. Verdugo:

This letter is the American Health Information Management Association's (AHIMA's) response to the Office for Civil Rights' (OCR's) request for information (RFI-75FR23214) regarding the HITECH requirements for the establishment of an expanded accounting of disclosures as published in the May 3, 2010 *Federal Register*. AHIMA is a non-profit professional association of more than 57,000 health information management (HIM) professionals.

HIM professionals are educated, trained, and certified to work with health information and data including the principles and concepts of confidentiality, privacy, and security (CPS). HIM professionals generally hold positions that include CPS functions, and HIM professionals are often the designated privacy or security officers in larger facilities and clinics covered by HIPAA or state CPS regulations. Usually, HIM professionals are in charge of release of information (ROI) and data in such organizations.

In addition to certification in CPS, AHIMA provides ongoing CPS education and training to the healthcare industry, emphasizing this commitment during its annual Privacy and Security Week each April. AHIMA addresses consumer concerns through its personal health record Web site,¹ community consumer training through its component state associations, and by issuing its Health Information Bill of Rights.²

AHIMA appreciates the OCR's desire for more information associated with the HITECH requirement for an expanded accounting of disclosure to include treatment, payment, and operations (TPO) for HIPAA entities using electronic health records (EHRs). This requirement is significant to the HIM profession because of our awareness of the difficulties tracking presents, the administrative

¹ www.myPHR.com

² http://library.ahima.org/xpedio/groups/public/documents/ahima/bok1_045343.pdf

burden we anticipate, and the limited use of such information to the individuals who request such a disclosure. This is not a question of an individual's right to know where their protected health information (PHI) is being disclosed, but rather of the implications such tracking will have on the ability of the overall healthcare system to treat the patient in a timely and appropriate manner and meet the requirements of both the system and the oversight groups to which it must report.

Our responses come from consultation with our professional staff and HIM professionals who volunteer for our various professional practice councils. Our comments are made in the order of the questions as presented in the RFI.

1. What are the benefits to the individual of an accounting of disclosures, particularly of disclosures made for treatment, payment, and healthcare operations purposes?

Approximately half of the states have a release requirement for treatment, payment, or operations (TPO)—and even among these states a request for an accounting of disclosures is rare. Comments that surfaced with regard to this question can be summarized as follows:

- Requests for accounting have been very rare. When such requests have been made, relative to TPO, it is often to confirm information was sent to the referring physician, a specialty practice or a facility to whom the patient has been referred; to a health plan or payer (and often to a specific individual at the payer or plan); or to another third party (which has a required release or court order).
- On rare occasions, an individual requests to know whether information was released to a third party whom the individual suspects is after their health information. Often, such a request concerns whether a third party has access to information (use) and not disclosure (as defined by HIPAA).
- The definitions of use and disclosure are still not understood not only by industry professionals across care or plan settings but also by individuals or patients.

In attempting to determine benefits to an individual, it was suggested that such an accounting, when performed correctly, might invigorate an individual to become better engaged in their healthcare.

2. Are individuals aware of their current right to receive an accounting of disclosures? On what do you base this assessment?

- Individuals are not specifically aware of what an accounting means, and rarely use the term even when requesting information that is, essentially, an accounting. Seldom has the given information provided the answer sought, since they may be interested in whether an individual at the provider or plan site has received or viewed the information disclosed rather than information that has been sent out.
- Individuals are informed of their rights at admission or intake, and this information is included in most if not all Notices of Privacy Practices (NPPS). However, our collective experience is that this information is not retained by most individuals. In certain circumstances, individuals may be

reminded of this right by facility personnel when an issue arises or the individual expresses an anxiety concerning privacy.

- As to the individual being aware of the new pending rights under HITECH: our collective experience is that few, if any, individuals are aware of this right unless a member of an organization seeking to explore such rights has contacted them.
- Most of our commenters have had no request for an accounting since the HIPAA rules went into effect. Of those that have, even large systems have had less than a half dozen requests since the beginning of the compliance period. This leads us to believe that individuals either do not know or understand this right, or have no desire or need for this information.

These comments are based on our experience. As noted above, HIM professionals staff most HIM or medical records departments in facilities, including large clinics. They, or a member of their staff, are typically responsible for responding to any request for an accounting of disclosures.

3. If you are a covered entity, how do you make clear to individuals their right to receive an accounting of disclosures? How many requests for an accounting have you received from individuals?

- The Notice of Privacy Practices is the means by which all our commenters' organizations inform individuals of their right to receive an accounting. In the rare situation where a request is made, there might also be a discussion about this right.
- As noted, most commenters' organizations have had no requests. A few have had only one or two since HIPAA became effective. AHIMA has not done a survey on this requirement for a few years, but when these surveys were done, the response was similar to that stated here.

4. For individuals who have received an accounting of disclosures, did the accounting provide the individual with the information he or she sought? Are you aware of how individuals use this information once it is obtained?

- In most cases raised in our discussions, individuals did not share whether they were satisfied with the information received.
- In a few cases, the individual wanted to know if a particular individual was either forwarded the information, or if they wanted to know who accessed the data at the facility.
- It has been our collective experience that when an individual was concerned about information being released through conversation, it was the individual or a close relative with whom they shared the information who caused the information to spread to unintended parties.

5. With respect to TPO disclosure, the rule provides the standard that an electronic health record system record the date, time, patient identification, user identification, and a description of the disclosure. The Office of the National Coordinator for HIT (ONC) also received a request to include to whom a disclosure was made and the reason or purpose for the disclosure....

Again, HIM professionals are generally in charge of ROI at facilities. Many privacy and security officers are also HIM professionals and it is with this experience that we are responding to the questions highlighted under Question 5. AHIMA believes in the right of individuals to understand the use of their health-related information. At the same time the standard defined for disclosure (what information must be collected at the time of use, including for disclosure), administration (the collection and input of information required by the standard), and retention (how long such use or disclosure information is kept) presents a significant expense and use of resources even in an organization with a fully electronic system.

Additional data requirements for the accounting of disclosures standard:

- Some of the required data is often not known since data is disclosed to organizations—other health providers, state agencies, health plans, or payers—rather than to a known, specific individual. Even if an individual’s name is given, we suspect it will be misused since the exchange of data occurs 24 hours a day and often cannot go through a specific individual. Likewise, the specific use for such data is not always known, especially when its release is requested by the individual.
- Some data is often seen or used by a number of individuals at the receiving organization. A sending organization has no way of knowing who beyond the receiving individual (if such a person can be identified) has seen or used the information once within the organization.
- Not all information is released (under TPO) electronically from the EHR. Eventually this might be the case, but not for several years. Currently, hybrid systems exist in most providers and health plans and the data media and flow vary by request, source, and requested media.
- We are concerned about information that may be released to a health information exchange organization (HIEO). Some HIEOs will have databases or warehouses, further complicating the collection of information required by the standard to respond to a request for an accounting. Some of our members suspect that once HIEOs are up and running, they might create an increased demand for disclosure information given individuals concerned with HIE. Clarification is needed on just how far down the chain of information—entity to HIEO or a business associate—data collection will need to go to respond to an accounting request.
- The standard or accompanying regulation needs to better define what constitutes a disclosure and the boundaries of a covered entity.

How important is it for the individual to know this information/data?

- In the cases where individuals have sought data and have indicated a concern that what they received was not enough, the data requested has been detailed and more in line with the new additions to the standards suggested in this question. It must be understood that the burden of supplying such detailed data increases costs, and also takes time away from clinical and administrative staff to enter such information in a system. At times this data input could jeopardize a timely response for the sake of compliance.

Generalized versus specific information?

- In many institutions it might be easy to generalize a purpose for the release depending on the staff member identified as releasing the information. However, this may be less than an individual might desire. Capturing the more in-depth information will be expensive both with regards to systems and administrative burden. Perhaps this expense should either be paid for in an overall increase of health rates, or through specific fees charged to the individual requesting this information.

Understanding of “Operations”

- There is considerable agreement that most individuals do not understand the meaning of “treatment,” “payment,” or “operations.” Operations can also vary from entity to entity, so they are it is not consistent in content. A few commenters related the difficulty they encountered when trying to explain quality measurement organizations, QIOs, and the like, to patients. When individuals desire additional information concerning the reason for a disclosure for operations, it adds to the entity’s burden and costs.
- In light of the new HITECH requirements the definition of operations could either be narrowed or a new definition that differentiates between required (external) disclosures and those made for the internal benefit of an organization. This might permit more transparency and less administrative burden, especially if the external reporting to government and quasi-government entities is exempt.

It must be noted that several of our commenters working in or with physician practices pointed out the significant burden this requirement might place on practices where the physician or other clinical personnel are required to gather and record this information.

6. For existing EHR systems:

(a) Is the system able to distinguish between “uses” and “disclosures”?

- This ability has not been demonstrated by most vendors, and our commenters are unaware of systems that can make this distinction.
- Many of the commenters pointed out that systems may be accessed by a variety of personnel for the purpose of disclosing information to an outside source. The purpose is not collected (only that the record is accessed), nor is there a process for inputting all this information from the various medical staff in a position to release information for treatment. The current HIPAA requirements are more easily identified since they are managed through a single source or two such as the emergency or HIM department.
- Existing systems often only exist in the HIM department to cover its release of information function. These systems therefore do not cover or identify other releases that may be made throughout the organization, especially for treatment and operations.

(b) If the system is limited...what information is recorded? Retention? Retention Burden?

- Audit logs record the date, time, user, and whether the user viewed the record, recorded documentation, or altered the record in some way. Few systems document purpose, but purpose can be determined to some degree by the accessor's functional status or role.
- If sending reports to physicians not in the institution's workforce constitutes a disclosure, then data must be collected to cover lab or diagnostic information, transcribed documents, and the records themselves for final sign-off. Note: Laws, such as those in California, prohibit the employment of physicians, therefore complicating the anticipated disclosure requirement.
- Many systems archive logs relatively quickly, and retention is much shorter than three years given existing requirements. Because of the current archive processes, the archive records must be searched to capture different encounters or admissions in some systems.
- Record retention for over three years is not an issue for our commenters. However, collecting information will be a significant effort and cost along with the cost of system changes.
- Please note that many entities already engage outside contractors to handle release of information functions because of limitations on resources in facilities. Implementing an accounting will either call for the inclusion of such contractors in the system, or for such contractors to add services to fulfill compliance. The latter option may not be possible due to the decentralized nature of disclosure as discussed above.

(c) If the system can distinguish between uses and disclosure of information...data elements

- None of our commenters know of an EHR system that includes a module capable of distinguishing between uses and disclosures.
- Our commenters noted that if disclosures are recorded—including those to other providers associated with the individual's care—tracking could get rather messy since physicians and, potentially, consulting physicians or HIEOs could in turn disclose information, and so on. Individuals would have to understand the scope of each discloser and therefore need the contact information of each entity in the chain.

(d) If the system can distinguish between uses and disclosure of information...standard descriptions.

- Our commenters were not aware of such a system in an EHR. However, there are independent systems for HIM departments using standard descriptions. Since these systems are independent, entry is manual.

(e) Centralized or decentralized systems?

- Our commenters are aware of both centralized and decentralized systems, and in some entities there can be a variety of combinations. Some of this determination depends on the definitions of "entity" and "workforce" as described in previous questions. Inclusion of "treatment" greatly adds to the confusion, because it is not unusual for a hospital or large clinic (physicians, nursing staff, social workers, and so forth) to be in contact with referring and consulting physicians,

external ancillary services, or referral services such as home health and long-term care, by phone or other media outside the EHR. Larger facilities also have numerous independent practices associated with the facility. In addition to treatment, these entities have their own payment and operations functions. In the past, especially in hospitals, it has been the practice to have the admission or registration staffs provide information and consents covering all these entities, to make the intake of the individual easier. Potentially, with this rule, each potential entity may feel the need to perform a separate admission or registration activity to ensure their compliance. This could prove too heavy a burden on the patient and the combined entities.

- Commenters from large systems also note that many of the distributed EHRs are different systems or come from different vendors. This means that any internal or separate module must be standardized if an accounting has to be system-wide.

(f) Does the system automatically generate an accounting for disclosure under the current HIPAA rules...

- As noted, we are not aware of an EHR system that does such a release. We are aware of release of information systems that record such disclosure, and these could be expanded. However, entry to the system is manual and as described above only covered the releases or disclosures controlled by the HIM department or other hospital or clinic departments.

7. The HITECH Act provides2011.

Will covered entities be able to begin accounting for disclosures through an EHR to carry out TPO by January 1, 2011?

- As noted, we are not currently aware of EHR software that would enable such accounting by January 1, 2011 (seven months from now). While there is separate software available, it would be a manual operation and subject to the concerns we addressed in previous questions.

If not, how much time for vendors....

- We do not have information as to the amount of time needed for this software to be added to a complete EHR, especially since this requirement is not part of meaningful use as proposed by the Centers for Medicare and Medicaid (CMS) in the January notice of proposed rulemaking, which is already putting significant demands on vendors.
- If a vendor were to develop a module that could be added to an existing system, it must be remembered that all access points to the system must be upgraded so that any member of the entity could access the module to document the detail required for the accounting of disclosure. In addition to the module being added and all entry ports revised (there could be thousands in a large facility), there would be significant training of the entire workforce associated with a potential release, including most clinical staff, interns, and residents, and many administrative staff members. This becomes more difficult depending on the definition of *entity* and *disclosure*. (Is an order to an outside entity carrying PHI, a disclosure?) The other alternative would be for a facility to funnel all TPO through one or more centers of release. Compliance enforcement would be significant in as much as we would anticipate individuals to “test” the system.

8. What is the feasibility of an EHR module just for disclosure?

In a facility:

- As noted, such “modules” or systems exist. Previously, we have described the shortcomings of such a module in large systems, and potentially in small practices, when disclosures can occur from multiple staff or departments.
- We also note that most current EHR systems are proprietary, making the interface of such a module very difficult.

Decentralized EHR systems:

- We were uncertain of the meaning of a decentralized EHR system as used here. If an EHR system were enterprise-wide (multiple hospitals and clinics) we believe the issues raised would be larger for implementation. However, if we are only tracking release outside of an enterprise, this could result in a lower volume if, for instance, the enterprise included physicians (primary and referral/specialists), long-term care services, ancillary services, and the like.).

9. Other information:

- Our commenters raise concern that if covered entities understand the accounting for TPO requirements and costs, and vendors cannot come up with feasible, affordable modules or systems, this requirement could create a barrier to entities seeking to engage in the meaningful use incentives programs under Medicare and Medicaid.
- Unfortunately, a module or system to account for disclosure produces little, if any, return on investment for covered entities, other than being in compliance with the rule. The lack of demand for such information in the past, along with the significant burden and cost to implement and maintain a system, presents a significant burden to marginal providers and plans. This requirement, as noted, will affect most staff in many covered entities. This is not a case of being compliant by merely following rules; this is a requirement that calls for additional functions to be added to existing clinical and administrative functions, with no compensation and little benefit even for the patient. We urge the OCR to consider how entities can recoup the costs associated with this requirement.
- Until vendors can produce and clinicians are willing to use an EHR/HIE system 100 percent of the time, we see no possibility for automatic accounting for disclosures. If any communication considered a disclosure is done outside the EHR system, an entry must be made and all the required data collected. Conceivably, a standard set of reasons, acceptable (meaning an individual required no additional information) to the individual, along with a limited need to describe who received the information, could simplify this task earlier, and lower the cost.
- Finally, what is an EHR? While there are definitions included in ARRA-HITECH, many organizations do not have a 100 percent non-paper, electronic record, nor are most EHRs a single system or module. Since most covered entities are neither completely electronic nor completely paper, how does a disclosure rule based on the EHR function in the current hybrid environment

in which most entities work? If the information disclosed (under TPO) is not contained in the electronic section of the record does it mean this disclosure does not have to be accounted for? What is the tipping point, especially as organizations move toward an electronic record, but at one module at a time? And, as we have noted before, what constitutes the entity, such that laboratory data being shared with an outside party for operations purposes would or would not have to inform the ordering physician of the detail of such a disclosure?

Conclusion

As noted at the beginning, we welcome the OCR's opportunity to comment on these issues. They are very important to the HIM profession as we struggle to answer many of these same questions and anticipate the forthcoming regulations in an environment responding to other sections of ARRA-HITECH and the recent healthcare reform legislation, a sluggish economy, and the cautious transformation to full EHRs.

We respect and support the individual's right to know how and where their protected health information is being disclosed. We believe that Notices of Privacy Practices should be clear on how data is collected, used, and, when necessary, disclosed outside the treatment circle in which the patient is served. Medicine is changing, and there are numerous experiments such as the Medical Home and HIE coming about for the benefit of the individual that raise new challenges in tracking the movement of PHI at a granular level.

Individuals have a right to trust the health information system and networks and many professionals including those in HIM are working hard to maintain the confidentiality of data in the maintenance of policies and the installation of good security systems and practices. These steps, along with strong enforcement of laws that punish the misuse of PHI or inappropriate discrimination associated with an individual's health information, should increase that trust. At this time, the nation's healthcare system is in a transformational stage, and as regulations are put in place they must balance individual rights with the cost of providing systems to be paid for by all. We are concerned that the data collection processes for disclosures, identified to date, not impede the purpose for which the information is being sent or requested. This is especially critical if the data being disclosed is associated with treatment. The propose regulations directing process must also be mindful of the costs, resources, and time needed to implement and maintain a system and process that does not appear to provide much benefit, even to the individual who wishes to use the system.

We trust these responses and comments are helpful, and stand ready to provide more information if possible. We contemplated a more formal survey of the profession. However, the time permitted and required cost prohibited us from doing so. We are willing to seek additional information if the OCR assists us. In the meantime, if there are further questions about this response, or other questions with regard to HIPAA, HITECH, or disclosures, please contact me at the address or phone number above, or at dan.rode@ahima.org. In my absence, please contact either Allison Viola, AHIMA's director for federal relations, at the same address and phone, or at allison.viola@ahima.org, or Harry Rhodes, AHIMA's director for practice leadership at (312) 233-1119, or harry.rhodes@ahima.org. We thank you for your time and consideration of these comments.

AHIMA Comments on ONC RFI
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Sincerely:

A handwritten signature in blue ink that reads "Dan Rode". The signature is written in a cursive style with a large, looping initial "D".

Dan Rode, MBA, CHPS, FHFMA, Vice President, Policy and Government Relations

Cc: Allison Viola, AHIMA
Harry Rhodes, AHIMA